BASF Corporation 8EHQ-0203-15290 **BASF**

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February 19, 2003

Attention: 8(e) Coordinator
U. S. Environmental Protection Agency
Document Control Officer
Office of Pollution Prevention and Toxic Substances, 7407
1200 Pennsylvania Avenue, NW
Washington, DC 20460

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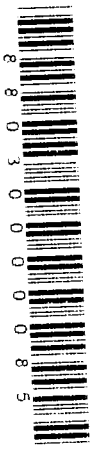
Ladies and Gentlemen:

Subject: Notice in accordance with Section 8(e). Results of 2 Prenatal Developmental Toxicity Screening Studies in Wistar Rats Conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany

BASF Corporation is submitting results of 2 prenatal developmental toxicity screening studies in Wistar rats with several Phthalates conducted by BASF Aktiengesellschaft, Ludwigshafen, Germany. Phthalates found to show indications for prenatal developmental toxicity were: Di-heptylphthalate (DHP) [CASRN 3648-21-3] and Di-hexylphthalate (DHxP) [CASRN 84-75-3]. Both studies were carried out based on the requirements of the following guidelines:



- EC Commission Directive 87/302/EEC of Nov. 18, 1987, Official Journal of the European Communities, No. L 133 (1988)
- OECD Guidelines for Testing of Chemicals, Proposal for Updating Guideline 414, Prenatal Developmental Toxicity (January 2001)
- EPA, Health Effects Test Guidelines; OPPTS 870.3700: Prenatal Developmental Toxicity Study (August 1998)

Each test substance was administered by gavage to 10 time-mated female Wistar rats/group at a dose of 1,000 mg/kg body weight on day 6 through day 19 post coitum. The control group used in each of the two studies was dosed with the vehicle only (olive oil Ph.Eur./DAB). At scheduled necropsy, 9 - 10 females/group had implantation sites. The fetuses were assessed for external, soft tissue and/or skeletal (including cartilage) findings without knowledge of treatment group.

Results:

Marked signs of maternal toxicity occurred in each test group dosed with one of the above mentioned phthalates and were substantiated by adverse clinical findings like salivation and/or vaginal hemorrhages, statistically significant impairments in food consumption, decreased absolute and corrected body weight gains and increased liver weights.

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Prenatal developmental toxicity occurred in the form of:

- total embryolethality (resulting in a postimplantation loss of 100%) after administration of 1,000 mg DHxP/kg body weight/day.

and

- reduced mean fetal body weights with findings being indicative for transient delays in fetal development (i.e., reduced skeletal maturation, dilated renal pelvis/ureter) and an increased overall malformation rate (e.g. cleft palate, hydronephrosis, malpositioned testis, various skeletal malformations) after administration of 1,000 mg DHP/kg body weight/day.

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Although the findings are not considered to present a substantial risk to human health or the environment, BASF Corporation understands that reporting of results from this study under TSCA 8(e) is in accordance with EPA's policy. Please note that BASF Corporation does not currently manufacture, process or distribute this chemical in the United States.

Very truly yours,

BASF CORPORATION

Edward J. Kerfoot

Edward J. Kerfoot, Ph.D.
Director, Toxicology and Product Regulations

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